SUBCOMMITTEE ON PUBLIC BUILDINGS AND GROUNDS

REGARDING H.R. 881: A BILL TO PROHIBIT SMOKING IN FEDERAL BUILDINGS

RESPONSE TO WRITTEN QUESTIONS OF CONGRESSMAN BILL EMERSON

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QUESTIONS

1. "Dr. LeVois, you have reviewed the statistical approach that EPA used in its ETS report, and you have heard the criticisms and defenses of that approach that have been offered today. You have had experience in the application of epidemiologic techniques to regulatory problems at another federal agency, the Centers for Disease Control. How does what the EPA did compare with what other agencies do? Is the EPA an aberration, or does the problem of policy-based science occur throughout the public health establishment?"

2. "As a non-scientist, I want to get an understanding of just what it means to shift the standard for statistical significance the way that EPA did. I don't know much about epidemiology, but I do know something about political polls.

(a) It is true, isn't it, that by doubling the possibility of error from 5 percent to 10 percent in the ETS studies the EPA was doing essentially the same thing as doubling the margin of error in a political poll from the typical plus or minus 5 points to plus or minus 10 points?"

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(b) I certainly wouldn't want to pay for a political poll that predicted results that could swing 10 points either way. What about health studies with such wide margins of error? Are they worth anything?"

ANSWERS

I hope to explain why I do not believe that the EPA has used statistics appropriately in their ETS risk assessment. My answers to Congressman Emerson's questions can be prefaced by the comments of two recognized authorities in the field of applied biostatistics concerning the use of what scientists refer to as "one-tailed" versus "two-tailed" tests of statistical significance:

J.L. Fleiss - "By performing a one-tailed test, [the researcher] is ruling out as unimportant the possible inference that p_1 [rate of disease in the exposed group] is significantly greater than p_2 [rate of disease in the unexposed group]."

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"...a one-tailed test is called for only when the investigator is not interested in a difference in the reverse direction from that hypothesized."

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"If, however, the investigator intends to report his results to his professional colleagues, he is ethically bound to perform a two-tailed test."

Page 21.

Joseph L. Fleiss. Statistical Methods for Rates and Proportions. New York: John Wiley & Sons, 1973.

P. Armitage - G. Berry

"The critical value for a one-sided test at level *P* is therefore the same as that for a two-sided test at level 2*P*. In a sense the distinction is semantic. On the other hand there is often a temptation to use one-sided tests rather than two-sided tests because the probability level is lower, and therefore the apparent significance is greater. A decision to use a one-sided test should *never* be made after looking at the data and observing the direction of the departure. Before the data are examined one should decide to use a one-sided test only if it is quite certain that departures in one particular direction will always be ascribed to chance, and therefore regarded as nonsignificant however large they are. This situation *rarely* arises in practice, and it will be safe to assume that significance tests should almost always be

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two-sided." Page 98.

P. Armitage and G. Berry. Statistical Methods in Medical Research. 2nd ed. Oxford, England: Blackwell Scientific Publications Ltd, 1987.

The EPA has not used an appropriate significance test for their meta-analysis of data from selected epidemiologic studies on the relationship of spousal smoking and lung cancer (the central analysis used by EPA to estimate an ETS/lung cancer risk), nor has the EPA adequately addressed fundamental problems in the data used for that analysis.

The first draft of the EPA's ETS risk assessment used a standard two-sided significance test for the main spousal smoking analysis. Had the same two-sided significance test been used in the revised EPA risk assessment the result would not have been statistically significant. In their final risk assessment the EPA shifted to a one-sided statistical test. This shift suggests that the EPA decided to use a one-sided significance test after reviewing the data and observing that a two-sided test did not achieve statistical significance. This is exactly the error that Armitage and Berry warn against.

A test of statistical significance is only an aid to decision-making. Such tests help to describe the level of confidence one has that a given result is not due to chance alone. The 95% or 99% confidence levels for significance tests are standards used by researchers both in federal agencies and the scientific community

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in general, in both epidemiology and risk assessment. The 90% confidence level used in EPA's ETS risk assessment would not be accepted by that Agency if it were, for example, submitted by a manufacturer as part of an application for an EPA-regulated pesticide. A one-in-ten error rate is simply not good enough, and should not have been used in the EPA's ETS risk assessment.

Prior to release of the EPA document new spousal smoking data were published in two studies, including the largest U.S. study, that brought the pooled lung cancer risk estimate down even further, to a level that would not be significant at even the 90% confidence level. Such statistical instability plainly contradicts EPA's claim of "medium to high" confidence in their ETS risk estimate, and underscores the need for higher scientific standards than they have employed.

Tests of statistical significance are valid aids in decision-making <u>only</u> if the underlying data are unbiased. The error EPA made by employing a one-sided, 90% significance test should not obscure a more basic and important error. The EPA has pooled results from spousal smoking studies that are not adequate to answer questions about possible health effects of ETS exposure. This is because spousal smoking is a biased proxy for ETS exposure. Spouses of smokers tend to have greater exposure to other lung cancer risk factors than do spouses of nonsmokers. The EPA attributes all of the reported spousal smoking-associated lung cancer risk to ETS exposure, even though it is clear that spouses of smokers tend to have poorer diets, lower socioeconomic status,

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and increased occupational exposures, and are more likely to have a history of prior pulmonary illness than are the spouses of nonsmokers. The EPA's ETS meta-analysis simply pools biases contained in the individual studies to produce a biased result.

Biases introduced when spousal smoking is employed as a proxy for ETS exposure could easily be responsible for the very weak reported pooled spousal smoking / lung cancer risk estimate. It is noteworthy that meta-analysis of results of studies that have looked at ETS exposure in the workplace (as opposed to using spousal smoking as the ETS exposure definition) shows no increase in ETS related lung cancer risk. This important discrepancy undermines both the validity of the spousal smoking proxy and the inference that ETS exposure causes lung cancer.

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